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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/688,076	10/13/2000	Philip A. Beachy	JHUC-P01-016	8453
28120	7590	08/24/2004	EXAMINER	
ROPES & GRAY LLP ONE INTERNATIONAL PLACE BOSTON, MA 02110-2624			LEWIS, PATRICK T	
		ART UNIT		PAPER NUMBER
		1623		

DATE MAILED: 08/24/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/688,076	BEACHY, PHILIP A.
	Examiner	Art Unit
	Patrick T. Lewis	1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
 THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 28 July 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) 11-19 and 21-41 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-10, 20 and 42 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 13 October 2000 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>03122002</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION***Election/Restrictions***

1. Applicant's election with traverse of Group V in the reply filed on July 28, 2003 is acknowledged. The traversal is on the ground(s) that the subject matter of the claims in Group XI could be searched simultaneously with the subject matter of the claims in Group V with no significant additional burden to the examiner. This is not found persuasive because a search for the compounds of Group V and the method of Group XI are not coextensive.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 11-19 and 21-41 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on July 28, 2003.

Claim Objections

3. Claims 2, 4, 6, 8, and 10 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The dependent claims read upon compounds wherein at least one variable is "absent". This added limitation is not seen to be within the scope

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of the independent claims which do not permit the absence of any of the recited variables.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Suginome et al. Bull. Chem. Soc. Jpn. (1981), Vol. 54, pages 3042-3047 (Suginome).

Suginome discloses the oxidized derivative of N-acetyljervine, compound 3 (Scheme 1, page 3043). Compound 3 reads upon the instantly claimed compounds wherein R₂ is =O, R₃ is CH₃, R₄ is =O, R₅ is H or not present, R₆ is CH₃, and R₇ and R'₇ are taken together to form a polycycle which includes a tertiary amine in the atoms which make up the ring.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which

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said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 1-10, 20, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suginome et al. Bull. Chem. Soc. Jpn. (1981), Vol. 54, pages 3042-3047 (Suginome) and Beachy et al. US 6,432,970 (Beachy) in combination.

Claims 1-2 are drawn to compounds of Formulae I. Claims 3-4 are drawn to compounds of Formula II. Claims 5-6 are drawn to compounds of Formula III. Claims 7-8 are drawn to compounds of Formula IV. Claims 9-10 are drawn to compounds of Formula V. Claim 20 is drawn to a pharmaceutical preparation comprising a compound of any of claims 1-10. Claim 42 is drawn to a pharmaceutical composition comprising a compound of Formulae I.

Suginome teaches the oxidized derivative of N-acetyljervine, compound 3 (Scheme 1, page 3043). Compound 3 reads upon the instantly claimed compounds wherein R₂ is =O, R₃ is CH₃, R₄ is =O, R₅ is H or not present, R₆ is CH₃, and R₇ and R'₇ are taken together to form a polycycle which includes a tertiary amine in the atoms which make up the ring.

Suginome differs from the instantly claimed invention in that Suginome does not explicitly teach pharmaceutical compositions.

Beachy teaches pharmaceutical compositions of compounds of Formulae I-VII which embrace the instantly claimed compounds (columns 19-28 and 47-50).

It would have been obvious to one of ordinary skill in the art at the time of the invention to formulate the compounds of Suginome into a pharmaceutical composition. Claiming an unpatentable compound in combination with a carrier does not render the combination patentable if it would be obvious in the prior art to utilize a carrier with the compound. As shown by Beachy, the use of carriers with the instantly claimed compounds was known at the time of the instant invention.

Conclusion

9. Claims 1-42 are pending. Claims 11-19 and 21-41 are withdrawn from further consideration as being drawn to a nonelected invention. Claims 1-10, 20, and 42 are rejected. No claims are allowed.

Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 571-272-0655. The examiner can normally be reached on M-F 10:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Patrick T. Lewis, PhD
Examiner
Art Unit 1623

ptl
August 19, 2004